IDPH IOWA Department of PUBLIC HEALTH
Protecting and Improving the Health of Iowans
Kim Reynolds, Governor | Adam Gregg, Lt. Governor | Kelly Garcia, Interim Director

COVID-19 Vaccine Information Brief

March 25, 2022

Changes to the document from the previous version are highlighted in yellow.

The next Vaccine Information Brief will be April 11, 2022

IMPORTANT/NEW COVID-19 Vaccine Information

- HRSA COVID-19 Uninsured Program and HRSA COVID-19 Coverage Assistance Fund
- FDA to Hold Advisory Committee Meeting on COVID-19 Vaccines to Discuss Future Boosters
- Clinical Guidance on Pediatric Needle Usage
- Preventing Fraud or Theft of COVID-19 Vaccines and Vaccination Cards
- Pfizer Controlant Data "SAGA Logger" Troubleshooting and Manual Upload Instructions
- Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training
- People Who Received COVID-19 Vaccine Outside the United States
- IRIS COVID-19 Provider Vaccine Inventory Management
- Shelf Life Extension for Johnson & Johnson's Janssen COVID-19 Vaccine
- Vaccine Expiration Date Resources
- V-Safe After Vaccination Health Checker

HRSA COVID-19 Uninsured Program and HRSA COVID-19 Coverage Assistance Fund

The HRSA COVID-19 Uninsured Program and HRSA COVID-19 Coverage Assistance Fund will soon stop accepting claims due to a lack of sufficient funds. Claims submitted by these deadlines will be paid subject to eligibility and availability of funds.

For the Uninsured Program, the deadlines to submit claims for each category of service are as follows:

- Testing claims: March 22, 2022 at 11:59 p.m. ET
- Treatment claims: March 22, 2022 at 11:59 p.m. ET
- **Vaccination claims: April 5, 2022 at 11:59 pm ET**

Per the Centers for Disease Control and Prevention's Requirements for COVID-19 Vaccination Program Providers, providers must continue to administer COVID-19 vaccines at no out-of-pocket cost to recipients.

Resources

- HRSA COVID-19 Uninsured Program Claims Submission Deadline FAQs
- https://www.hrsa.gov/covid19-coverage-assistance
- Provider Support Line at 1-833-967-0770; for TTY dial 1-888-970-2920.
    - Hours of operation are 8:00 a.m. to 8:00 p.m. ET, Monday through Friday

FDA to Hold Advisory Committee Meeting on COVID-19 Vaccines to Discuss Future Boosters

The U.S. Food and Drug Administration announced a virtual meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) on Wednesday, April 6, to discuss considerations for future COVID-19 vaccine booster doses and the process for selecting specific strains of the SARS-CoV-2 virus for COVID-19 vaccines to address current and emerging variants. **No vote is planned at this meeting and there will not be any discussion of any product-specific applications.**

Along with the independent experts of the advisory committee, representatives from the U.S. Centers for Disease Control and Prevention and the National Institutes of Health will participate in the meeting. The April 6 VRBPAC meeting is intended to assist the agency in developing a general framework that will inform its regulatory decision-making on:

- What might warrant updating the composition of COVID-19 vaccines to address specific variants.
- Timing and populations for COVID-19 vaccine booster doses in the coming months.

The FDA intends to livestream the VRBPAC meeting on the agency's YouTube channel; the meeting will also be webcast from the FDA website.

Clinical Guidance on Pediatric Needle Usage

The Advisory Committee on Immunization Practices recommends using a 1-inch needle for children 1 year of age and older when administering vaccines to ensure the vaccine is deposited well into the muscle tissue. A 5/8-inch needle may be used in some circumstances if the child's skin is stretched tightly, and subcutaneous tissues are not bunched.

Providers should use professional judgment and for the rare situation in which a 5/8-inch needle is required, one can be obtained from the facility's inventory and replaced with supplies from the ancillary supply kits. Ancillary kits contain only 1-inch needles. Please refer to the following webpages for more guidance:

- Needle gauge and length, all ages:
  - https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf
- IM injection, infants:
  - https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-Infants-508.pdf
- IM injection, 1-2 years
  - https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-1-2-Years-508.pdf
- IM injection, 3-6 years:
  - https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-3-6-Years.pdf

General Best Practice Guidelines on Immunizations **- ACIP Vaccine Administration Guidelines for Immunization | CDC**

Preventing Fraud or Theft of COVID-19 Vaccines and Vaccination Cards

To prevent COVID-19 Vaccination Cards from being stolen, fraudulently reproduced, and illegally sold to reflect full vaccination status for someone who has not received a COVID-19 vaccine, please consider the following strategies:

- Always secure **COVID-19 vaccine vials and vaccination cards** to protect them from inappropriate distribution.
- Monitor both the inventory of COVID-19 vaccine and blank vaccination cards and keep them locked up when not being used.

IDPH encourage reporting suspected fraud and theft incidences to local law enforcement agencies and to the HHS Office of Inspector General and/or the FBI as listed below:

- HHS Office of Inspector General (1-800-HHS-TIPS or www.oig.hhs.gov)
- Federal Bureau of Investigation Electronic Tip Form (http://tips.fbi.gov)

Surplus Vaccination Cards

Please shred or destroy unused surplus cards. If unable to do so, providers must keep extra vaccination cards in a secure location (under lock and key).

Pfizer Controlant Data "SAGA Logger" Troubleshooting and Manual Upload Instructions

For troubleshooting any issues with the logger (e.g., no signal, low power mode, blank display), Controlant's Receiving Instructions Website a range of logger instructions. In case network issues persist, go to Controlant's Data Upload Website, and follow the guidelines below to perform a manual upload prior to returning logger.

If the temperature monitoring device is unable to connect with the cell network, please follow the steps below. These steps allow Points of Use (POUs) to ensure proper data connection through a manual data upload using local internet networks. The manual data process steps are the same for both Controlant 10.01 and/or Controlant SAGA loggers.

Step 1.

Connect the temperature monitoring device to a computer that has access to the local network using the USB cable provided with the temperature monitoring device. Manually upload the temperature monitoring data onto the computer.

Step 2.

The data file will upload onto the computer in the form of a *.bin file*. Once locating the .bin file on the computer, please manually upload this file to https://upload.controlant.com/. Manually uploading the data to this website, this allows the data from the temperature monitoring device to reach the Pfizer Control Tower which helps to ensure supply chain visibility.

Step 3.

Once the data is received at the Control Tower, a quality disposition report is created which documents quality considerations and identifies any suspected nonconforming items. Do not use the product until a quality report from Controlant advising on further use has been received.

Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training

At this time, the Medical Affairs team is continuing to educate providers on Purple, Gray, and Orange caps as well as medical updates. To access dates and links for upcoming training sessions, please visit: **https://www.pfizermedicalinformation.com/en-us/medical-updates.**

People Who Received COVID-19 Vaccine Outside the United States

The recommendations for people vaccinated outside of the United States depend on the vaccine(s) received for the primary series, whether the primary series was completed, and whether a booster dose was received.

For people who received all FDA-approved or -authorized COVID-19 vaccines, Pfizer-BioNTech COVID-19 Vaccine can be used in people ages 5 years and older and Moderna COVID-19 Vaccine can be used in people 18 years and older to complete vaccination.

For people who received at least one COVID-19 vaccine that was not FDA-approved or -authorized, Pfizer-BioNTech COVID-19 Vaccine can be used in people ages 12 years and older and Moderna COVID-19 Vaccine can be used in people ages 18 years and older to complete vaccination. For further guidance, refer to Appendix A. People who received COVID-19 vaccine outside the United States in the Interim Clinical

Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States.

Table Aii: Received a COVID-19 vaccine listed for emergency use by WHO but not approved or authorized by FDA*†

Vaccination history	Recommended actions	Special situations
Received all recommended primary doses for that vaccine	• Do not repeat primary series • Administer mRNA booster dose at least 5 months after last primary series dose	People ages 12 years and older who are moderately or severely immunocompromised should also receive: • A single dose of an mRNA COVID-19 vaccine at least 28 days after receiving the last dose of the non-FDA-approved or -authorized primary series. • An mRNA booster dose at least 3 months after last primary series dose, for a total of four vaccine doses.
Received partial primary series for that vaccine	• Administer a single dose of an mRNA COVID-19 vaccine at least 28 days after receipt of their first dose to complete primary series • Administer mRNA booster dose at least 5 months after last primary series dose	People ages 12 years and older who are moderately or severely immunocompromised should also receive: • A single dose of an mRNA COVID-19 vaccine at least 28 days after the last dose of the primary series. • An mRNA booster dose, at least 3 months after last primary series dose, for a total of four vaccine doses.
Received a booster dose after completion of primary series	• Do not repeat booster dose	

Table Aiii: Received a heterologous primary series composed of doses of a COVID-19 vaccine listed for emergency use by WHO, at least one of which is not FDA-approved or authorized*†

Vaccination history	Recommended actions	Special situations
Received two doses of vaccine	• Do not repeat primary series • Get mRNA booster dose at least 5 months after last primary series dose	People ages 12 years and older who are moderately or severely immunocompromised should receive: • A single dose of an mRNA COVID-19 Vaccine at least 28 days after receiving the last dose of the primary series. • An mRNA vaccine booster dose, at least 3 months after last primary series dose, for a total of 4 vaccine doses.
Received a booster dose after completion of primary series	• Do not repeat the booster dose	

Table Aiv: Received all or some of the recommended doses of COVID-19 vaccines that are NOT FDA-authorized, FDA-approved, or among those listed for emergency use by WHO

Vaccination history	Recommended actions	Special situations
Received any number and combination of vaccine doses	• Doses received do not count toward vaccination in the US • Start primary series at least 28 days after the last dose of vaccine • Get mRNA booster dose at least 5 months after completion of primary series	People ages 12 years and older who are moderately or severely immunocompromised should: • Restart the series, following guidance for this group around number and timing of primary series dose(s) and booster vaccination.

*The EUI provides a legal framework for heterologous use of mRNA COVID-19 vaccines (i.e., Pfizer-BioNTech and Moderna) in people who received a non-FDA authorized or approved COVID-19 vaccine outside of US.

†COVID-19 vaccines that are listed for emergency use by WHO that are not FDA-authorized or FDA-approved have not been evaluated for efficacy or safety by CDC or ACIP

Resources

- COVID-19 Vaccine Listed for Emergency Use by WHO
- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

---

IRIS COVID-19 Provider Vaccine Inventory Management

IRIS vaccine inventory management is a critical component of the pandemic vaccine response. All COVID-19 Vaccine Providers are required to report COVID-19 vaccine doses administered to IRIS which deducts from IRIS inventory. Maintaining accurate inventory impacts the state's ability to report accurate inventory to federal partners. Additionally, this also impacts the state's vaccine thresholds and the amount of vaccine available for all providers. Providers should make it a practice to regularly check inventory for expired vaccine and immediately remove expired inventory to prevent it from being administered. Please review these IRIS inventory management best practices to ensure accurate vaccine inventory.

- Ensure Vaccine Redistributions are accurately reported.
    - All COVID-19 vaccine transfers between providers MUST be completed and approved by IDPH. Please see the *Vaccine Redistribution Instructions*.
    - Providers should NOT physically transfer COVID-19 vaccine without prior IDPH approval.
- Verify all data entry in IRIS is up to date.
    - Doses administered are required to be reported to IRIS within 24 hours of vaccine administration.
- Verify data exchange between IRIS and the organization's Electronic Health Record (EHR) has worked appropriately.
    - IRIS Admin users can use the *Doses Not Deducted Report* to view and update doses of COVID-19 vaccines not deducted from IRIS inventory.
- Report vaccine wastage in IRIS.
    - Verify all vaccine wastage is documented appropriately using the approved adjustment reasons included in the *Adjusting COVID-19 Vaccine Inventory for Wastage* instructions.
    - **VACCINE WASTAGE ADJUSTMENT REASONS CANNOT BE USED TO CORRECT VACCINE INVENTORY FOR UNACCOUNTED DOSES**.

If you have questions regarding IRIS and vaccine inventory, contact the IRIS Help Desk at 1-800-374-3958.

Shelf Life Extension for Johnson & Johnson's Janssen COVID-19 Vaccine

The Food & Drug Administration announced the approval of a shelf life extension for the Johnson & Johnson's Janssen COVID-19 vaccine for **an additional three months**. The shelf life of this vaccine has been updated from 6 months to **9 months**. This shelf life extension applies to refrigerated vials of J&J/Janssen COVID-19 vaccine that have been held in accordance with the manufacturer's storage conditions.

This shelf life extension applies to all inventory dated to expire on March 7, 2022 or later. Vaccines dated prior to March 7, 2022 should be disposed of accordingly and reported as waste according to the COVID-19 provider agreement. **Vaccine providers should visit the Janssen COVID-19 Vaccine Expiry Checker webpage to confirm the expiration dates**.

COVID-19 vaccines authorized under an EUA do not have fixed expiration dates, and expiration dates may be extended as more stability data becomes available. This decision is based on data from ongoing stability assessment studies, which have demonstrated that the vaccine is stable at 9 months when refrigerated at temperatures of 36° - 46° Fahrenheit (2° - 8° Celsius). Healthcare providers should always check the manufacturer's website to obtain the most up-to-date expiration dates for the COVID-19 vaccines in inventory.

Reporting vaccine wastage in IRIS:

- Verify all vaccine wastage is documented appropriately using the approved adjustment reasons included in the *Adjusting COVID-19 Vaccine Inventory for Wastage* instructions.
- **VACCINE WASTAGE ADJUSTMENT REASONS CANNOT BE USED TO CORRECT VACCINE INVENTORY FOR UNACCOUNTED DOSES**.

If healthcare providers have questions regarding IRIS and vaccine inventory, contact the IRIS Help Desk at 1-800-374-3958.

Vaccine Expiration Date Resources

Always be sure to check the manufacturer's website to obtain the most up-to-date expiration dates for COVID-19 vaccines. It is important for healthcare providers to update vaccine expiration dates in IRIS. Questions regarding IRIS vaccine inventory and adjusting expirations dates can be directed to the IRIS Helpdesk at 800-374-3958.

For EUA COVID-19 vaccines that do not have a final expiration date, the CDC has set an expiration date of 12/31/2069 to serve as a *placeholder date*. Such vaccines have a dynamic expiration date, which can change over time as additional stability data become available. This placeholder date, which is far in the future, is intended to serve as a prompt for the provider to check the latest expiry information on the manufacturer's website. **It is important for healthcare providers to update vaccine expiration dates in IRIS.**

The Pfizer COVID-19 vaccine:

It is important for all healthcare providers to double check all shelf life extensions for all Pfizer products. Pfizer does not have an expiration date look up tool for these vaccines. The date on the label is **NOT** the expiration date, instead, each vial has the lot number and date of manufacture printed on the label. Pfizer does provide guidance for expiration dates on their website**.**

- Regardless of storage condition, GRAY CAP and ORANGE CAP vaccine vials should not be used after 9 months from the **date of manufacture** printed on the vial and cartons.
- The PURPLE CAP vaccine vials with an **expiry date** of September 2021 - February 2022 (printed on the label) may remain in use for 3 months beyond the printed date if vials are maintained in approved storage conditions (-90°C to -60°C, -130°F to -76°F).
- Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 (ORANGE CAP) years of age may be stored at refrigerated temperatures between 2°C and 8°C (36°F and 46°F) for up to 10 weeks. **Vaccine initially distributed is nearing or has met the 10-week beyond-use date (BUD).**
    - **Reminders for providers:**
        - Vaccine may be stored in a refrigerator unit between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.
        - Do NOT use vaccines stored in the refrigerator after 10 weeks. Discard appropriately.

- Use a tracking system to ensure the vaccine is not used after the BUD. CDC has tracking labels to monitor storage times at [Pfizer-BioNTech COVID-19 Vaccine (5 Through 11 Years of Age) | CDC]

Expiry information for Ages 5 through 11 DILUTE BEFORE USE Orange Cap presentation and Ages 12 years and older DO NOT DILUTE Gray Cap presentation

Printed Manufacturing Date	9-Month Expiry Date
06/2021	28-Feb-2022
07/2021	31-Mar-2022
08/2021	30-Apr-2022
09/2021	31-May-2022
10/2021	30-Jun-2022
11/2021	31-Jul-2022
12/2021	31-Aug-2022
01/2022	30-Sep-2022
02/2022	31-Oct-2022

Expiry information for Ages 12 years and older DILUTE BEFORE USE Purple Cap presentation

Printed Expiry Date	Updated Expiry Date
September 2021	December 2021
October 2021	January 2022
November 2021	February 2022
December 2021	March 2022
January 2022	April 2022
February 2022	May 2022

Janssen COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to www.vaxcheck.jnj/

Moderna COVID-19 vaccine:

The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Go to www.modernatx.com/covid19vaccine-eua/

CDC's COVID-19 Vaccine Expiration Date Tracking Tool can help providers keep track of the expiration date by lot number.

V-safe After Vaccination Health Checker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources.

- V-safe information sheet and poster: posted on the vaccine webpage and available in 5 languages: English, Spanish, Korean, Vietnamese, and Simplified Chinese
- V-safe after vaccination health checker website
- V-safe Print Resources
- V-safe Poster-11x17
- Vaccine Adverse Event Reporting System (VAERS)